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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,605	12/04/2003	John F. Shanley	032304-089	6950

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,605

Applicant(s)

SHANLEY, JOHN F.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 28 and 42 recite the limitation "wherein the hinge length is smaller than the hinge thickness" in line 2.

Claim Objections

1. Claim s 33, 34, 47, 48, and 55 are objected to because of the following informalities: Claims 33, 47 and 55 recites the limitation "a strut" in line 4. Claims 34 and 48 recite the limitation "axial struts" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 29-30, 32-34, 43, 44, 46-48, 53-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

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subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The limitations in claims 29 and 43, "the hinge width is smaller than the hinge thickness" and "the hinge width is no greater than 60% of the hinge thickness" are not disclosed in the specification. The limitation in claims 30, 44 and 53, "the hinge width is at least 50% smaller than the beam width" is not disclosed in the specification. The limitation in claims 32, 46 and 54 "the hinge width is $\frac{2}{3}$ the beam width is not disclosed in the specification. The limitation in claims 33, 47 and 55 "extends less than 10 percent of a length of a strut" is not disclosed in the specification. The limitation in claims 34 and 48, "a length of the axial struts is 1:6 or less" is not disclosed in the specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 33, 47 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which direction the cross sectional area is taken and so it is also unclear what is meant by the statement "an abrupt transition, which extends less than 10 percent of a length of a strut. Furthermore there is a lack of antecedent basis for the limitation "a strut" in line 4.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 27-33, 35-47, 49-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 10-23 and 25-26 of U.S. Patent No. 6,241,762. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely using synonymous language to claim the same limitations.

7. Claims 27, 38, and 50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7, 11 and 16 of U.S. Patent No. 6,293,967 in view of Klein (USPN 5,922,020). The patent discloses all of the limitations in the claims except for the ductile hinges being in the shape of a curved

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beam having first and second arcuate surfaces facing the same direction with the second arcuate surface being larger than the first. Klein discloses the limitations that are missing from the patent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the curved hinges to ensure uniformity upon opening of the stent (Col 2, lines 39-40).

8. Claims 27, 38, and 50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 11 and 16 of U.S. Patent No. 6,562,065 in view of Klein (USPN 5,922,020). The patent discloses all of the limitations in the claims except for the ductile hinges being in the shape of a curved beam having first and second arcuate surfaces facing the same direction with the second arcuate surface being larger than the first. Klein discloses the limitations that are missing from the patent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the curved hinges to ensure uniformity upon opening of the stent (Col 2, lines 39-40).

9. Claims 27-29, 31, 33-38, 39-42, 44-45, 47-50, 53, 55, 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 30-41 of copending Application No. 11/126,850. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely using synonymous language to claim the same limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 27, 30, 32-34, 36-41, 44, 46-48, 50-55 are rejected under 35

U.S.C. 102(e) as being anticipated by Klein (USPN 5,922,020).

12. Klein discloses a stent with a plurality of beams (32) and plurality of ductile hinges (42) in the shape of a curved beam having first and second arcuate surfaces facing the same direction with the second surface larger than the first. The hinge width is at least 50% or 2/3 smaller than the beam width (Fig. 7A). There is an abrupt transition between the cross sectional area of the struts and the cross sectional area of the ductile hinges that extends less than 10% of the length of the beam. The ratio of the length of the hinge to the length of the beam is less than 1:6. The ductile hinges are asymmetrical (Fig. 7a where the line of asymmetry goes from the top of the figure to the bottom) and are configured to reach a first and second predetermined strain level where the first is larger. The ductile hinges are configured so that upon compression during

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crimping, the strain will be distributed along the first arcuate surface and upon expansion, the strain will be distributed along the second arcuate surface.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Kusleika (USPN 5,722,979).

15. Klein discloses the claimed invention as stated above.

16. Klein does not disclose the device is expandable by a balloon.

17. Kusleika discloses a balloon catheter that is used to deliver stents where the balloon inflation pressure ranges from 2 to 6 atmospheres (Col 2, line 56-57 and Col 3 lines 28, 46, 62).

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a low pressure delivery balloon to deliver a stent in order to minimize potential medical complications such as balloon rupture, or damaging healthy tissue if the balloon is improperly placed (Col 1, lines 24-40). Kusleika offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

19. Claims 35, 49 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of MacGregor (USPN 4,994,071).
20. Klein discloses the claimed invention as stated above.
21. Klein does not disclose a beneficial agent for delivery to the patient.
22. MacGregor discloses that a stent can be coated with surface treatments to provide for the elution of drugs.
23. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate drug delivery into the stent. It is well known in the art to deliver drugs to the stent site to prevent restenosis and or to heal diseased tissue. The inventions are analogous with each other and the instant invention and therefore the combination is proper.
24. Claims 28, 29, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein.
25. Klein discloses the invention as stated above. Klein does not disclose that the hinge width is at least 60%.
26. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the hinge width smaller than the hinge thickness because Applicant has not disclosed that the hinge width being smaller than the hinge thickness provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have

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expected Applicant's invention to perform equally well with hinge width not being smaller than the hinge thickness because it would still be able to act as a deformable hinge to receive the strain during compression and expansion.

27. Therefore, it would have been an obvious matter of design choice to modify Klein to obtain the invention as specified in the claim.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allen et al (USPN 6,773,455).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh




ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

11/12/05